Proceedings of the Integrated Crop Management Conference

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The Impact of FDA Traceability Rules on Iowa Agriculture

Charles R. Hurburgh Jr.
Iowa State University, tatry@iastate.edu

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Charles R. Hurburgh, Jr., professor, Agricultural and Biosystems Engineering
Professor in Charge, Iowa Grain Quality Initiative, Iowa State University

Abstract

In June of 2006, the Food and Drug Administration will begin enforcement of new bioterror related recordkeeping rules for food products. Handlers and shippers of food products (including bulk grains) will be required to keep records of the origin and type of food received, and to whom the food products were then sold or delivered. Tracking grain from farmers through to end users will present major challenges, but also will support other market-driven requests for traceability, purity and food safety. This session will present the regulations as they apply to farmers, grain handlers and processors and will offer some initial steps toward meeting the requirements.

The Impact of FDA Traceability Rules on Iowa Agriculture

Dr. Charles R. Hurburgh, Jr.
Professor, Agricultural Engineering
Iowa State University
November 30, 2005

Traceability

Traceability is the ability to trace the history, application or location of an entity by means of recorded identifications.

- Document chain-of-custody
- Document production practices (eg. organic)
- Meet consumer desires or social preferences
- Provide due diligence for safety/quality assurance
- Respond to security threats or regulations
- Protect integrity of brand name
- Authenticate claims (eg. Bordeaux wine)

Certification

Auditable documentation of activities (paper trail)

eg. Tkt 101 to Annex 2; Annex 2 to Flat; Flat to Train BN3246

Verified by independent third party

Contrasts with test and pay strategy of commodity markets

Differentiated Markets

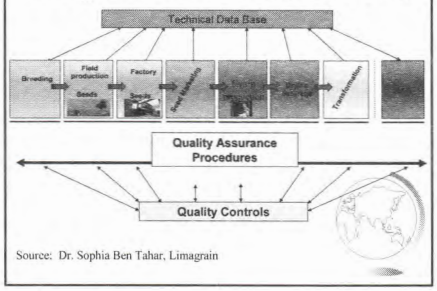
Preserve an economically valuable trait

- Organic
- Low trans or saturated fat
- Pharmaceutical

Keep out an undesirable or unhealthy trait

- Unapproved GMO
- Unwanted GMO
- Toxic substances (natural or deliberate addition)

Limagrain Corn Production Chain



Source: Dr. Sophia Ben Tahar, Limagrain

Traceability (EU Program)

Traceability entails the ability to trace products through the production and distribution chains. Operators must have systems in place to transmit and retain (5 years) information about GMOs or GM products.

The general objectives are to facilitate :

- **targeted monitoring of potential effects on environment or human health**
- **withdrawal of products should unforeseen risk be established**
- **control and verification of labelling claims**

Source: INRA 2003

Technically unavoidable traces of GMOs in food or feed

Regulation allows the adventitious presence of authorized GMOs up to a maximum of 0.9 %

Except:

- **Tolerance (0.5% threshold, 3 years) only for GMOs assessed by the EU Scientific Committees as safe.**

  Example: RR Corn (NK603 event)

- **Tolerance 0.0% for "unknown" GMO**

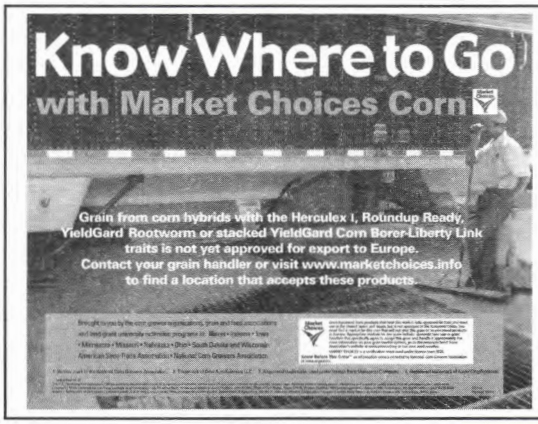
  Example: Herculex Corn (Cry1F event)

- **Operators must demonstrate appropriate steps to avoid the presence of GMOs or residues thereof**

Source: INRA 2003

We are an alliance of family farmers whose process has been certified under ISO 9001-2000 standards.

Asoyia 1% Low-linolenic Soybean Oil



USDA Security Plans

- Protect grain from tampering
- Vulnerability assessment
- Procedures for:
  - Physical security
  - Shipping, receiving
  - Action in emergency
  - Contacting authorities

U.S. Department of Health and Human Services
FDA Food and Drug Administration

Overview of Bioterrorism Act Establishment and Maintenance of Records Final Rule

Leslye M. Fraser, Esq.
Director, Office of Regulations and Policy
Center for Food Safety and Applied Nutrition

Regulatory Development of Rule

- **Proposed rule published May 9, 2003 (68 FR 25188)**
- **212 timely submissions received during comment period raising 220 major issues**
- **Final rule published Dec. 9, 2004 (__ FR _____); http://www.fda.gov/oc/bioterrorism/bioact.html**

Definitions (cont.)

Food: Definition in sec. 201 (f) of the Federal Food, Drug, and Cosmetic Act applies:

- *i.e., "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."*

What Foods Does FDA Not Regulate?

- Foods to the extent they are under the *exclusive* jurisdiction of the U.S. Department of Agriculture (USDA) under the:
  - Federal Meat Inspection Act (21U.S.C. 601 *et seq.*)
  - Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or
  - Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*)

Definitions (cont.)

- **Transporter:** person who has possession, custody, or control of an article of food in the U.S. for the *sole purpose* of transporting the food, whether by road, rail, water, or air.
- Includes a foreign person that transports food in the U.S., regardless of whether that foreign person has possession, custody or control of that food for the sole purpose of transporting that food.

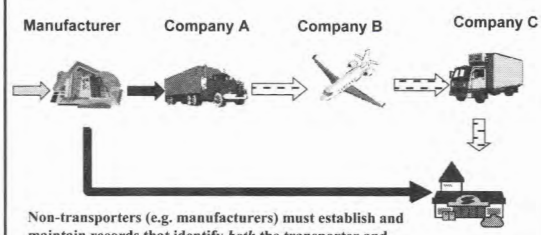
Definitions (cont.)

- **Non-transporter:** a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation

Who is excluded from all of the regulations in this subpart?

- Farms
- Foreign persons, except for foreign persons who transport food in the United States
- Restaurants

Establishment and Maintenance of Records by Non-Transporters



Non-transporters (e.g. manufacturers) must establish and maintain records that identify *both* the transporter and non-transporter IPS and ISR (indicated with solid red arrows above)

Records Non-transporters Have To Establish And Maintain to Identify the Immediate Previous Source (IPS)

Non-transporters have to establish and maintain records to identify the non-transporter *and* transporter IPS of all food you *receive* that include:

- Firm name and contact information of the non-transporter IPS (domestic or foreign)
- Description of type of food received, including brand name and specific variety

Records Non-transporters Have To Establish And Maintain to Identify the IPS (cont.)

- Date food was received
- For persons who manufacture, process, or pack food, the lot or code number or other identifier (to the extent the information exists)
- Quantity and how the food is packaged (e.g., 25 lb cartons)
- Firm name and contact information of the transporter IPS who brought the food *to* you

Records Non-transporters Have To Establish And Maintain to Identify the Immediate Subsequent Recipient (ISR)

Non-transporters have to establish and maintain records to identify the non-transporter *and* transporter ISR of all food you *release* that include:

- Firm name and contact information of the non-transporter ISR (domestic or foreign)
- Description of type of food released, including brand name and specific variety

What Information Must Non-Transporters Keep in Records to Identify the ISR (cont)?

- Date food was released
- For persons who manufacture, process, or pack food, lot or code number or other identifier (to the extent this information exists)

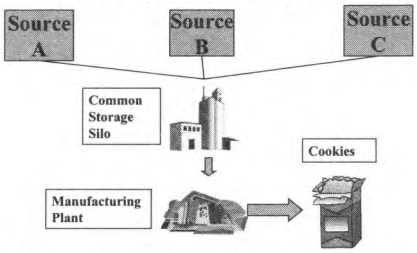
What Information Must Non-Transporters Keep in Records to Identify the ISR (cont)?

- Quantity and how the food is packaged (e.g., 25 lb cartons)
- Firm name and contact information of the transporter ISR who transported the food *from* you

Non-transporters' Records Regarding the ISR

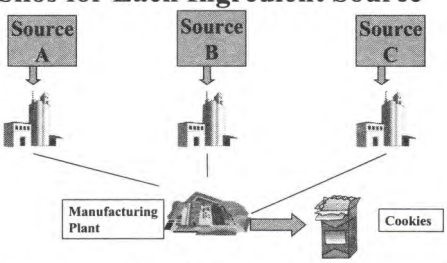
- Records must include all information *reasonably available* to you to identify the specific source of each ingredient that was used to make every lot of finished product
  - What is reasonably available may vary from case to case

Example 1: Common Storage Silo for An Ingredient (e.g., Flour)



Information reasonably available is the identity of <u>all potential sources</u> of the flour for each finished product

Example 2: Dedicated Storage Silos for Each Ingredient Source



Information reasonably available is the <u>identity of the specific source</u> of the flour for each finished product

Record Retention Periods

Food having significant risk of spoilage, loss of value, or loss of palatability within . . .	Non-transporter Records	Transporter Records
60 days	6 months	6 months
> 60 days but within 6 months	1 year	1 year
> 6 months	2 years	1 year
All animal feed, including pet food	1 year	1 year

Traceability in Bulk Grain Handling

- Initial bin assignment for every inbound scale ticket
- Data fields for other information related to scale ticket
- Date, time stamp to establish position within bin
- Date, time record of in-house transfers
  - From bin xx, to bin xx
  - *Automation records time start, gates % open*
- *Loadout scale records flowrate (time to fill), % gate openings.*
- LIFO, FIFO, NIFO or simulation flow?
- Traceability Index = 5 – 15

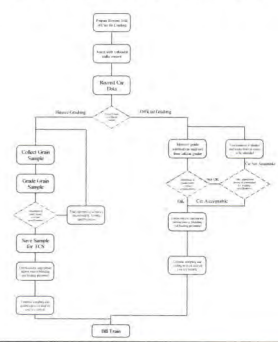
TI = Sum of Possible Sources/Amount to be Traced

Traceability Connection?

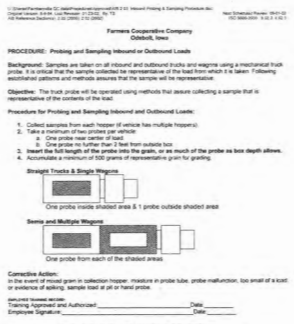
- Producers records → Handler's records
  - Example: 2004-411957-911857
  - Year, latitude, longitude, seed lot, connect with field records for production history.

Basic traceability – isolation of health/safety problems to a reasonable precision for public protection.

Basic Actions - Flowcharts



Basic Actions – Procedures



Farmers Cooperative Company
Odebolt, Iowa

PROCEDURE: Probing and Sampling Inbound or Outbound Loads

Background: Samples are taken on all inbound and outbound trucks and wagons using a mechanical truck probe. It is critical that the sample collected be representative of the load from which it is taken. Following established patterns and methods assures that the sample will be representative.

Objective: The truck probe will be operated using methods that assure collecting a sample that is representative of the contents of the load.

Procedure for Probing and Sampling Inbound and Outbound Loads:

1. Collect samples from each hopper (if vehicle has multiple hoppers).
2. Take a minimum of two probes per vehicle:
   a. One probe near center of load.
   b. One probe no further than 2 feet from outside box.
3. **Insert the full length of the probe into the grain, or as much of the probe as box depth allows.**
4. Accumulate a minimum of 500 grams of representative grain for grading.

Straight Trucks & Single Wagons

One probe inside shaded area & 1 probe outside shaded area

Semis and Multiple Wagons

One probe from each of the shaded areas

Corrective Action:
In the event of mixed grain in collection hopper, moisture in probe tube, probe malfunction, too small of a load or evidence of spiking, sample load at pit or hand probe.

EMPLOYEE TRAINING RECORD:
Training Approved and Authorized: _____ Date: _____
Employee Signature: _____ Date: _____

Basic Actions – Where Did You Put It?

- Initial bin assignment for every scale ticket
- Time-date stamp if possible
- Deliverer (transport ID)

2005-12-01:08:35, FC25698, 13-20054, 38
Date/time **ID** **Transport** **Bin**

- In-house transfer records: Amount, date/time, where to.
- Regular measurements to verify records

Basic Actions – Where Did You Put It?

What about a Producer?

2004-411957-911857-xx @ 2005-10-03:17:32
To Bin 5, Wagon 4, 525 bu

Bin 5, 2005-12-01:08:35, Tkt FC25698, 13-20054

Source, Date/time, amount, transport ID

Basic Actions – Mock Recall

Farmers Cooperative Elevator Company
Commodity Grain Recall Report

Date: July 1, 2041

Lot ID: CY 384228, 71 cars of soybeans shipped June 28, 2041 to Sharps, Calvin, IL

Origin of Product:
Sharps, Inc., Calvin, IL exported a 317 Iowa Mississippi River barge, [illegible] to us, [illegible] in the center [illegible] of the 1,500 rail car sample when [illegible] Elevator [illegible] The sample will be treated aside but been analyzed [illegible] result were [illegible] Six sample probes for this car. Grain from this car and [illegible] been sold [illegible] Sharps facility (12,500 bu) and in several [illegible] Sharps. No [illegible] found in any other sample from this area.

There have been no previous [illegible] from shipments [illegible] to Sharps and one Excel in the [illegible] past seven [illegible] have been [illegible]
Documentation: Railcar [illegible] from Sharps and [illegible] compartment [illegible] and [illegible]

Source Grain:
Origin CY 6,743 bushels [illegible] 500 grain [illegible] 2,852. Of this, 153,491 bushels shipped from [illegible] the empty to be loaded on May 15, 2002 when the previous load [illegible] Farmers Cooperative and Loaded. Loading [illegible] received her 57,100 bushels load. Destination [illegible] 17,340 bushels was received directly to [illegible] 75,000 bushels of soybeans [illegible] 500 bushels of sample grade. Drive [illegible] and 100 [illegible] were transferred from the [illegible]
Documentation: [illegible] Warehouse Receipt Agricultural [illegible]

Shipping Grade:
The grade is the [illegible] bushels from 71,000 bushels of Spruce receipts, 75,852 bushels transferred from [illegible] 2,000, 31,000 bushels from Six Grove to Oakville, and 500 bushels from Cedar to Oakville. The 1,700 bushels received during loading represented two farmer deliveries to the [illegible]. The grain had been transferred from Pemberville to Toledo, [illegible] were tested. [illegible] 37% of the 4,000 on hand as of June 25, 2041. The sample grade [illegible] from [illegible] had 2,642 bus between clearance of the 37. The 1,642 bushels [illegible] were transferred from Bin 3 to were reserved at Spruce.
Documentation: [illegible] Inside Inbox inventory: 017442 - 9/2/2002
Iowa Company Transfer Summary: 5,271 – 4/21
Bin Entry Ticket for Bin 37 Closeout

EMPLOYEE TRAINING RECORD:
Training Approved and Authorized: _____ Date: _____
Employee Signature: _____ Date: _____

The AG9000 Vision

- Develop an industry-specific approach that leads to ISO certification
- Recognize that agriculture has unique challenges and requirements
- Build market recognition that growers are prepared and positioned to participate
- Promote quality-assured commodities to create demand and economic returns
- This became ISO 22002 in August.

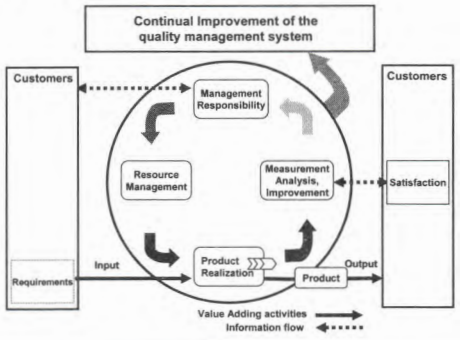
ISO 22002
Quality Management Systems

- Guidance on the application of ISO 9001:2000 for crop production

ISO 22002 Project Scope

- Goal is to create an international standard that provides guidance for the use of ISO 9001:2000 in crop production
- ISO22002 does not address:
  - Livestock
  - Food Safety
  - Off Farm Transport and Storage of Agricultural Products
  - Processing
  - Other

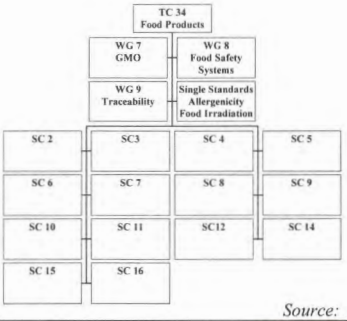
The Process Approach



International Standards

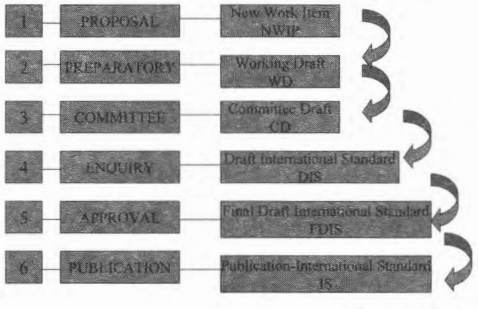
➢ ISO 9000-2001	QMS Design
➢ ISO 9004	Guideline Design
➢ ISO15161	Food and Beverage
➢ ISO 2200x	Food Production
➢ ISO TC34, WG7	Biotech testing
➢ ISO TC34, WG9	Traceability
➢ ISO TC34, WG12	Crop Production

TC 34 Organization



Source: AOCS

Stages in ISO Standard Development



Source: AOCS

Summary

- Tracing food to its origin is a growing world trend.
- Traceability serves several functions related to product quality, safety, security and authenticity.
- **FDA bioterror rules will cause increasingly precise product tracking.**

Summary

- Begin basic actions and documentation now.
- Look for operational efficiencies at the same time
- Expect international standards to develop.
- Bulk grains will not be exempt; the best system will become the standard.

Where to Find Us:

www.iowagrain.org